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December 20, 2002

VIA FACSIMILE AND REGULAR MAIL

John M. Taylor, III
Associate Commissioner for Regulatory Affairs
Food and Drug Administration
PKLN Bldg., rm. 1490 (HFC-1)
5600 Fishers Lane
Rockville, MD 20857

Re: Alcavis International, Inc. Citizen Petition - Docket No. 75N-183H Comment
No. CP13

Dear Mr. Taylor:

This letter is an interim response to a letter from you dated November 14, 2002. In that letter, you stated that the Citizen Petition ("CP") filed by our company, Alcavis International, Inc., does not present information showing U.S. marketing history for sodium hypochlorite 0.10 to 0.50 percent as a patient preoperative skin preparation so as to be included in the Tentative Final Monograph ("TFM") for Over-the-Counter ("OTC") Healthcare Antiseptic Drug Products.¹

We believe that FDA has prematurely and erroneously concluded that the CP did not present adequate U.S. marketing history to support the use of sodium hypochlorite 0.10 to 0.50 percent as a patient preoperative skin preparation and that the filing of a Time and Extent Application ("TEA") is inappropriate. Clearly, FDA's review was merely preliminary in that a closer look at the information and references in the CP provide the necessary evidence of the uses of this ingredient since World War I for site access or "cut-down" purposes. Such uses are a subset of what FDA later characterizes as preoperative skin preparation.

We are preparing a more detailed explanation of the information already contained in the CP and its references that addresses the use of sodium hypochlorite 0.10 to 0.50 percent as a patient preoperative skin preparation well before 1972. Due to my recent health related problems that resulted in surgery, our response to you has been slightly delayed and you should be expecting our correspondence within next few weeks.

75N-183H

LET 34

¹ See, Federal Register of June 17, 1994, Vol. 59 p. 31402. (59 FR 31402).

John M. Taylor, III
December 20, 2002
Page 2

In the meantime, if you have any questions, please feel free to contact me.

Very truly yours,

A handwritten signature in cursive script, reading "Ludovico Giavotto" followed by a stylized flourish or set of initials.

Ludovico Giavotto

cc: Dockets Management Branch
(Docket No. 75N-183H)